

PURPOSE

This Mobile Dental and PA161 Operations Guide outlines the protocol for the Oral Health Program (OHP) when conducting mobile dental facility permit and PA 161 program monitoring activities.

Public Act 161 of 2005 Public Dental Prevention Program and Public Act 100 of 2014 Mobile Dental Facility require the following:

IN GENERAL

In order to determine whether eligible entities comply with all federal, state, and local laws, administrative rules, regulations, and ordinances applicable to the operation of a mobile dental facility and PA 161 approvals, the individuals and entities that provide preventative or comprehensive dental services at the mobile dental facility, or PA 161 site including, but not limited to those concerning sanitation, infectious waste management and disposal, occupational safety, and disease prevention, the Department may conduct any of the following reviews of eligible entities:

- A random onsite review of each entity within a 3-year period.
- Follow-up reviews including prompt return visits to eligible entities, and their programs, that fail to meet the goals, standards, and requirements established by the Michigan Department of Health and Human Services-Oral Health program.
- Complaint reviews.
- Other reviews as appropriate, including reviews of entities with programs that have had other Federal, State, or local provider allegations and those that have been terminated for cause.
- Follow-up reviews upon cessation of operation.

Under the Public Act 100 of 2014 Mobile Dental Facility, and Public Act 161 of 2005 Public Dental Prevention Program, an Act to amend 1978 PA 368, the Department has both the authority and the responsibility for effective oversight of eligible entities that receive a mobile dental facility permit, or PA 161 program status. The Department has established monitoring procedures that ensure an appropriate level of accountability and quality among the eligible entities.

**MONITORING
PROCEDURES**

This Monitoring Procedures Guide will ensure the oral health services and programmatic integrity of the mobile dental facility permit and PA 161 entities receiving approval from the Michigan Department of Health and Human Services – Oral Health Program (OHP). To ensure this objective is realized, the OHP will conduct due diligence prior to the approval of mobile dental facility permits and PA 161 programs and perform appropriate and necessary post-approval monitoring activities. Receiving program approval advocates good intent and ensures that services are carried out in a manner consistent with all federal, state, and local laws, administrative rules, regulations, and ordinances included within the eligible entities' approved application. The OHP has implemented a performance-based framework for developing a monitoring strategy that integrates the observation method and type of monitoring activity conducted for each entity. This strategy is designed to measure relative factors across approval for each entity and to prioritize a set of monitoring activities by program assessment categories. Random agency site visits are conducted to evaluate and score each agency and is the basis of this framework.

Agency Assessment Criteria

The following criteria are assessed for each entity depending on type of permit (mobile dental facility permit and/or PA 161 program):

1. Length of entity approval status.
2. Type of population servicing.
3. Type of services provided.
4. Location of services (fixed or mobile), including counties serviced.
5. Dental provider list and information.
6. Referral protocol and written plan and procedure for providing emergency follow-up care.
7. Signed Memorandum of Agreement (MOA) if follow-up services are **not** within reasonable distance for the patient, or if the operator provides only preventative dental services.

8. Proof of general liability insurance covering the entity.
 9. Patient registration, health history, HIPAA Privacy Notice, and patient/parent/guardian consent form.
 10. Infection control procedures (Based off CDC guidelines for infection control in Dental HealthCare Setting, and Organization for Safety, Asepsis and Prevention (OSAP) guidelines).
 11. Organizational standards.
 12. Mobile dental facility equipped with, or appropriate access to, all of the following:
 - An instrument sterilization system.
 - Potable hot and cold water or hand sanitizer.
 - Toilet facilities.
 - Smoke and carbon monoxide detectors, as applicable.
 - Radiographic equipment properly registered and inspected, as applicable, by the state.
 - A communication device continuously available for making and receiving telephone calls and summoning emergency services.
 - Proper lighting.
 - Portable suction.
 - Hand pieces.
 - Dental instruments.
 - Supplies.
 - Prior agency assessment status.
- PA 161 program **only**:
- Evidence of non-profit status.
 - Supervision protocol.

- Sealant retention protocol.
- Protocol for Child/Elder abuse reporting.

ORAL HEALTH SERVICES MONITORING

Oral Health Services Monitoring addresses the content and substance of the programs. It is a qualitative review to determine performance, compliance, and risk. It assesses whether approved entities are compliant with statutory regulations and other policy guidelines. Oral Health Services Monitoring also involves quantitative review by monitoring administrative activities including compliance with program terms and conditions.

PROGRAMMATIC MONITORING

Programmatic monitoring is a thorough review of the mobile dental, and/or PA 161 entity's oral health service performance, and includes communicating with staff to discuss data in submitted documents, activities, and report status for the following purposes:

- Ensuring that the documents are complete, and reports support approved activities.
- Determining if the agency is in compliance with the program guidelines.
- Determining if activities of the mobile dental facility permit, or PA 161 approval are being implemented properly.
- Assessing complaints of the eligible entity to identify any problems.

Follow-Up/ Focused/ Complaint Review

If follow-up is needed, send correspondence to the entity requesting specific documents with a timeframe to respond or their non-response will be listed in the monitoring report/management decision letter. Typically, these types of reviews are generated by a high-risk assessment category or a corrective action plan/quality improvement plan.

OHP will conduct follow-up and corrective action plan/technical assistance plan reviews, including prompt return visits to eligible entities and their programs that fail to meet rules, standards, and requirements. OHP will conduct other reviews as appropriate, including reviews of entities with programs that have had other federal, state, or local violations other than assistance provided under the mobile dentistry or PA 161 program, or that have been terminated for cause.

MONITORING REVIEW – GENERAL PROVISIONS

The OHP will monitor mobile dental facility permit and PA 161 program entities in the areas listed below in addition to other federal, state, and local policies.

1. As required by Act 100 of 2014, MCL 333.21607, Mobile Dental Facility Permit Application Requirements include:
 - A list of each dentist, dental hygienist, and dental assistant who will provide care at or within the mobile dental facility, including, at a minimum, each individual's name, address, telephone number, and state occupational license number.
 - A written plan and procedure for providing emergency follow-up care to each patient treated at the mobile dental facility.
 - If the operator does not provide for follow-up services at a site within a reasonable distance for the patient, a signed memorandum of agreement between the operator and at least one dentist or party who can arrange for or provide follow-up services at a site within a reasonable distance for the patient. The memorandum of agreement shall state that the contracting dentist or party will accept referrals of patients treated at the mobile dental facility. The agreement to accept a referral does not require the dentist or party to treat the patient.
 - If the operator provides only preventative dental services, a signed memorandum of agreement for referral for comprehensive dental services between the operator and at least one dentist or party who can arrange for or provide comprehensive dental services to the patient within a reasonable distance for the patient.

- Proof of general liability insurance covering the mobile dental facility that is issued by a licensed insurance carrier authorized to do business in this state.
2. An operator shall meet **all** of the following requirements:
 - Comply with all federal, state, and local laws, regulations, and ordinances applicable to the operation of a mobile dental facility, including, but not limited to, those concerning radiographic equipment, flammability, sanitation, zoning, and construction standards, including standards relating to required access for persons with disabilities.
 - Maintain continuously available at the mobile dental facility a communication device for making and receiving telephone calls and summoning emergency services.
 - Make immediately available, upon request from any person, a copy of the license of each dentist, dental hygienist, or dental assistant working at the mobile dental facility.
 - Make immediately available, upon request from any person, a copy of the permit required under this part.
 3. An operator shall meet all of the following requirements:
 - The operator of a mobile dental facility and the operator's agents and employees shall comply with all federal, state, and local laws, administrative rules, regulations, and ordinances applicable to the mobile dental facility and to the individuals and entities that provide the preventative dental services or comprehensive dental services at the mobile dental facility, including, but not limited to, those concerning sanitation, infectious waste management and disposal, occupational safety, and disease prevention.
 4. An operator shall not provide dental services at a mobile dental facility unless it is equipped with, or there is appropriate access to, all of the following functional equipment:
 - An instrument sterilization system.
 - Potable hot and cold water or hand sanitizer.
 - Toilet facilities.

- Smoke and carbon monoxide detectors, as applicable.
 - Radiographic equipment properly registered and inspected, as applicable, by the state.
 - A communication device continuously available for making and receiving telephone calls and summoning emergency services.
5. An operator shall not provide dental services at a mobile dental facility unless it is equipped with, or there is appropriate access to, all of the following:
- Proper lighting.
 - Portable suction.
 - Hand pieces.
 - Dental instruments.
 - Supplies.
6. A written treatment plan shall include, at minimum **all** of the following:
- The name of the operator.
 - The permanent address of the operator.
 - The telephone number that a patient may call 24 hours a day for emergency calls.
 - A list of the services to be provided.
 - A statement indicating that the patient, parent, or guardian understands that treatment may be obtained at the patient's dental home rather than at a mobile dental facility and that obtaining duplicate services at a mobile dental facility may affect benefits that he or she receives from private insurance, a state or federal program, or other third-party provider of dental benefits.
7. Each person receiving dental services at a mobile dental facility shall receive **all** of the following information:
- The name of the dentist, dental hygienist, dental assistant, or party who arranged for or provided the dental services to the patient.

- The telephone number that patients may call 24 hours a day for emergency calls.
 - The telephone number or emergency contact number to reach the mobile dental facility or operator in case of emergency.
 - A list of the dental services rendered.
 - A description of any further dental services that are advisable or that have been scheduled.
 - A referral to a specialist, dentist, or party who can arrange for or provide comprehensive dental services if dental services cannot be provided at the mobile dental facility. Upon request of the dentist or party who accepts the referral, the operator shall transmit all imagery records taken of the patient at the mobile dental facility.
8. The operator or his or her designee shall notify the department not later than 30-days after any of the following occurrences:
- A change in the mobile dental facility operator.
 - A change in a memorandum of agreement.
 - A change in the address or telephone number of the mobile dental facility operator.
 - Cessation of operation of a mobile dental facility.
 - Any memorandum of agreement entered into after obtaining a permit.
9. Upon cessation of operation of a mobile dental facility, the operator shall do **all** of the following:
- Provide written notice to all treatment venues and, upon request, provide evidence of the written notice to the department.
 - Provide for availability of each active patient's dental records by one of the following methods:
 - Make the dental records available to the patient or the patient's parent or guardian for 180 days after the

mobile dental facility ceases operation and, upon his or her request, transfer the records to the active patient, the patient's parent or guardian, or another dentist.

- Transfer the records to another dentist.
 - Notify each active patient or the patient's parent or guardian that the dental records are available as required under subdivision (b), including the name and contact information for the dentist if the records have been transferred.
 - Upon request from the department, provide documentation that a reasonable attempt was made to contact each active patient or the active patient's parent or guardian to provide information concerning storage and retrieval of the patient's records. Additional follow-up will be attempted if necessary.
10. Monitoring of the PA 161 Program will ensure compliance with the following requirements:
- Is a public or nonprofit entity, or a school or nursing home that administers a program of dental care to a dentally underserved population.
 - Employs or contracts with at least one dentist or one dental hygienist.
 - Submits a program overview indicating the approximate population to served, the method by which the service is to be provided, the procedures for program oversight and direction, and the name and license number of the dentist and dental hygienist, if applicable, who are performing services under the program.
11. Administrative systems and procedures for both Mobile Dental Permit and PA 161 Programs include the following:
- Provider records retention protocol.
 - Infection control procedures.
 - HIPAA Privacy policy.

- Confidentiality and Protected Personal Information (PPI) protocol.
- Licensing and provider information.
- Patient registration/health history/consent form.

PA 161 ONLY:

- Non-profit status.
- Supervision acknowledgement form.
- Supervision protocol.
- Sealant retention protocol.
- Protocol for child/elderly abuse reporting.
- State of Michigan fiscal quarterly reports.

12. Program Monitoring Review for both Mobile dentistry and PA 161 programs includes the following:

- Eligibility/approval and renewal.
- Feedback and reporting.
- Public welfare health & safety.
- Quality assurance.
- Training & technical assistance.
- Qualifications and certifications.
- Staff or entity changes.
- Complaints.

**MONITORING
PROCESS**

In order to determine whether eligible entities meet the program guidelines, administrative rules, standard of care, infection control requirements, and other requirements (memorandum of agreements, referral process, radiation safety, and any other applicable policies), the following monitoring process will be followed:

A) Entity Assessment

The department will conduct random entity assessments to review compliance with mobile dental and PA 161 requirements.

A periodic entity assessment will be conducted annually. Coordination of the assessment will be with the contact person. Entity assessments are updated during the permit approval period, including onsite or office reviews. Based upon the assessment

score, the OHP may increase monitoring frequency. The qualitative entity assessment score uses the following categories:

- Low Risk.
- Moderate Risk.
- High Risk (Significant Failures reported to LARA/BOD/Medicaid/etc.).

B) Monitoring Plan and Schedule

OHP will develop and implement a monitoring plan and schedule based on the entity assessment categories. The monitoring plan and schedule defines the type of monitoring to be conducted. The score is subject to change any time during the year. Modifications to the monitoring plan and schedule may result.

Significant Failures, as defined by the Michigan Department of Health and Human Services (MDHHS) Oral Health Program, means a finding that the eligible entity is not in compliance with Federal or State law or administrative rules; or that the eligible entity has committed fraud, is risking or endangering the safety, health and well-being of the public, or an employee. All significant failures must be reported to the MDHHS and/or the associated department within the State of Michigan.

C) Monitoring

Monitoring is conducted as outlined in the monitoring plan using this monitoring procedures guide.

OHP will conduct monitoring visits, a random on-site review of each entity at least once during the two or three year permit period depending on approval dates. Note: monitoring consists of a programmatic, oral health services and infection control review. The OHP's goal is for all monitoring visits to be conducted within the required two-to-three-year approval period.

Follow-up reviews including prompt return visits to eligible entities and monitoring of their programs that fail to meet the goals, standards, and requirements established by OHP.

Other reviews as appropriate, including reviews of entities with programs that have had other Federal, State, or local provider allegations or terminated for cause.

Complaint Reviews:

OHP receives the complaint to review. When findings are listed in the complaint, the OHP requests a response from the entity. The OHP reviews the findings and the entity's response. The source of the complaint will be provided a copy of the OHP's decision for their records.

Monitoring Steps

Monitoring consists of three phases: 1) the pre-monitoring review plan; 2) the monitoring review; 3) post-review tasks.

1. **The Pre-Monitoring Review plan** – prior to arrival the OHP will:
 - Conduct site visit location agency communication. This communication is conducted with the site location point of contact, agency director, or staff and is used to establish expectations for the monitoring and ascertain issues and concerns from the site visit location agency.
 - Obtain mobile dental or PA 161 entity schedule for possible dates.
 - Schedule the onsite/other visit (from 1 month to 2 weeks prior to monitoring).
 - Send a confirmation correspondence to the entity confirming the review (confirm the date(s) and get contact information), including a memo to the site location agency.
 - Review entity files and data maintained.
 - Request any necessary documents.
 - Develop a list of information, documents, and activities to be reviewed and questions to ask the entity.
 - Compile materials to take to the onsite visit.

Pre-Monitoring Preparation

Prior to the actual onsite monitoring visit, the OHP conducts a number of tasks that include, but are not limited to, the pre-monitoring entity assessment and review of any past: monitoring reports and/or corrective action(s). Adequate

preparation prior to a visit provides the OHP monitors with the background information necessary to conduct a thorough visit. Prior preparation also helps to ensure that the entity can assist the OHP with relevant information about the programmatic, oral health services and infection control review of the PA 161 or mobile dental program, as well as provide a comprehensive overview of the status of the program.

2. **The Monitoring Review** – during the review, the OHP will:

- Communicate with site visit location point of contact. A Pre-monitoring Agency Questionnaire is conducted with the site location point of contact is used to establish expectations for the monitoring and ascertain issues and concerns from the site visit location organization.
- Conducts an oral health services, and programmatic review. The OHP monitors will review the entity's documents to ensure that all information contained therein is current and other requirements have been satisfied.
- Conducts interviews, observations and evaluates information.
- Hold an exit interview. The exit interview is conducted with the entity point of contact and designated personnel. The exit interview discussion is used as an opportunity for the entity to ask questions and to discuss issues identified during the site visit.

3. **Post-Review/Contact** – OHP will:

- Follow-up with the entity on any remaining items during the monitoring visit. (30 days from site visit.)
- Prepare and send the monitoring report to the entity. (60 days from site visit– the OHP admin staff will send out a draft report to the oral health director for a five-day review period prior to the official copy being issued.)
- Recommend training and technical assistance, if appropriate, to help the eligible entity correct deficiency(s).
- Follow-up with the entity until all findings, quality improvement plans, and corrective action plans have been resolved (follow-up may extend through the length of the expiration of the permit).

- Send a close out letter to signify all issues have been resolved.

MONITORING COMPONENTS

Monitoring components may include but are not limited to the following:

- Interview staff, dental providers, and site location point of contact.
- Conduct an office tour.
- Observe PA 161 or mobile dental procedures.
- Review PA 161 quarterly reports to access the following:
 - Review of actual services provided for the quarters, or fiscal year.
 - The number for patients seen.
- Review corporate documents, such as articles of incorporation, 501c3 status, provider licenses and other corporate documents in preparation for an on-site visit.
- Examination of the eligible entity's written policies and procedures for infection control, referral protocol and written plan and procedures for providing emergency follow-up care, mobile dental facility, or dental clinic equipment and supply inventories.

MONITORING DOCUMENTATION AND REPORTING

Field Notes:

1. OHP monitors shall complete Site-Visit Provider Notes when conducting site-visits. The Site-Visit Provider Notes align with a rubric measuring tool. The rubric was created to equally assess individual programs and identify potential risk(s).
2. The OHP monitors must submit all support documentation collected to complete the monitoring review. Support

documentation includes emails, reports, prior monitoring reports, and other items collected.

3. Field notes are required for all reviews.

Site-visit Rubric and Scoring Method:

A rubric is a scoring tool that explicitly represents the performance expectations for a mobile dental, and/or PA 161 program. [The Rubric Metric Guide for Site-visit Provider Notes](#) divides the objectives into risk levels and provides clear descriptions of the characteristics of the objectives associated with each area, at varying levels of risk. This scoring rubric is used to delineate consistent criteria for site-visit review. The rubric is also used to evaluate the criteria in the Site-visit Provider Notes with accurate and fair assessment.

Each section has possible points in 3 levels of risk category (Low, Moderate & High). The total points for each section are determined by the level of risk observed during the site-visit. Points are determined by the highest risk category (Example, if all points fall in the low risk except one, then it will be considered moderate risk). The points for each risk level are totaled at the bottom of each section. The total points for each section are calculated and divided by the total points possible to get the final, overall risk level.

Descriptions in **bold** are considered higher risk to program operations, public safety and/or violations of any federal, state, and local laws, administrative rules and/or regulations. During the site-visit, the Oral Health Program Monitor has the authority to immediately suspend operations if two or more **bold** actions are observed. If there are violations of three or more **bold** D areas, it will constitute immediate loss of permit.

Monitoring Reports Components:

1. Monitoring report must have a report memo addressed to the oral health director. The oral health director will sign the memo upon review and approval of the report. The report memo must contain:
 - Entity's name.
 - Entity's address, phone number, and email address.
 - Entity contact person's name.

- Type of monitoring.
 - Monitoring location.
 - Monitoring reporter's name.
 - Date of monitoring (including start and end date).
 - Status of the entity based on the risk assessment.
 - Mobile dental facility permit number.
 - List of providers with license number and contact information.
 - Findings, including any recommendations or failures.
 - Date of next monitoring if applicable.
2. The report must contain at least the following:
- Pre-monitoring and monitoring review description (date and name of attendees).
 - Purpose of visit.
 - Prior findings section.
 - Listing of observations, administrative recommendations, and findings. Each item must include the following appropriate categories:
 - Findings administrative recommendations numbered in sequence.
 - Title.
 - Description.
 - Failure.
 - Recommendation – if appropriate indicate the following:
 - **Quality Improvement Plan (QIP):**
Use Quality Improvement Plan language for minor findings that can be corrected onsite or within 30 days.

- **Corrective Action Plan (CAP):**
Use Corrective Action Plan language when entity cannot make corrections using a CAP or if the finding is a serious deficiency. A CAP with permit suspension may be in effect until evidence of corrections are completed. A CAP may last through permit renewal. Sanction/fine(s) may be applied.
- Training(s) and Technical Assistance provided. Include the following:
 - A description of the training and technical assistance provided.
 - Dates of training and technical assistance.
 - Attendees of training.
 - Recommendations of next training and technical assistance needed, if appropriate.

Submit to the oral health director with field notes for approval within 30 days of the monitoring review. Ensure all support and justification for findings are included as attachments.

MDHHS – Oral Health Program Decision Letter:

MDHHS – Oral Health Program Decision letter must be addressed to the Entity Operator. The Oral Health Director will sign the letter upon review and approval of the letter. The cover letter must contain:

- Monitoring reporter's name.
- Entity's name.
- Date of monitoring (start and end date as necessary).
- A summary of the findings listed in the monitoring review, including all categories.
- A summary of the entity's response.
- The MDHHS's response based on the review completed. Each finding must conclude with a statement indicating whether the finding has been resolved or not. For findings

that have not been resolved, a recommendation must be made together with an expected timeline and a due date for response to the OHP.

Close Findings (Close-out) Procedure:

The following close-out activities must be completed prior to closing a finding:

1. The OHP monitor will clearly document the finding(s) with all support documentation. The finding notes should be labeled and match the same numbering in the monitoring report. Example: Monitoring report finding 1 should have a corresponding addendum labeled finding 1.
2. The OHP monitors may be required to make follow-up visits to thoroughly examine the finding(s). Additional documentation may be necessary.
3. Each finding must contain a summary of events and a timeline of the underlying process.
4. Every finding must contain the appropriate federal, state, or local laws, administrative rules, regulations, and ordinances citation.
5. The OHP monitors will work to assist the entity in making corrections quickly for all findings found. Whenever possible, findings should be resolved during the monitoring visit.
6. The OHP monitor will summarize the finding in the monitoring report. Instructions on corrective action and follow-up must be provided with a due date. Typically, the due date is within 30 days, but it may be longer or shorter depending on the finding.
7. Once the monitoring report is issued, it is the entity's responsibility to respond to all findings as instructed. Upon receipt of an entity response, the OHP monitor will review the material to determine if the finding is resolved. A decision is sent to the entity within 30 days of the receipt of the entity's response. The decision letter will clearly identify resolved and unresolved findings. Once all the findings are resolved in a monitoring review, the OHP will send the entity a close-out letter.

**GUIDING
PRINCIPLES****Mutual Respect**

In working with mobile dental or PA 161 operators, staff, and consultants, the OHP values and recognizes the unique knowledge, ability, and independence of each person. The OHP is committed to treating all persons fairly and maintaining credibility by matching actions with words.

Open Communication

Effective communication is key in facilitating good working relationships with entities, and the OHP is committed to keeping lines of communication open. The purpose of communication is to assist in developing solutions to problems, to share program improvement ideas, and provide information on new developments in the underserved dental field. The OHP is open to contact and is committed to listening to suggestions/concerns and to gaining an understanding of entity operations and to assist entities in pursuing priorities.

Joint Problem Solving

The OHP operates under the basic belief that a team approach to problem solving is in the best interest of all parties involved. The OHP sincerely believes that collectively the OHP and the entity can arrive at the best solution to any situation. Through a team approach to problem solving, the OHP believes the team will come up with the best strategies for program development, conflict resolution, or compliance issues. The OHP wants to promote an environment in which the OHP and all mobile dental and PA 161 programs will be open to change and can work together in exploring options and developing mutually agreeable solutions.

Responsibilities

As a PA 161 program, or mobile dental facility permit holder, eligible entities have a duty to be accountable for the timely receipt of reports; to proactively address problems that impede the effective implementation of programs; and to institute effective internal controls to improve compliance. Monitoring and technical assistance are conducted in a professional manner with consistency, clarity, respect, timeliness, and two-way communication. Every monitoring visit is a learning experience for the OHP staff and the entity.